DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-005/S-001

Bioglan Pharma, Inc.
Attention: James M. Ciciriello
Regulatory Affairs Manager
7 Great Valley Parkway
Suite 301
Malvern, PA 19355

17 AUG 2001

Dear Mr. Ciciriello:

Please refer to your supplemental new drug application dated May 17, 2001, received May 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Solaraze (diclofenac sodium) Gel, 3%.

We acknowledge receipt of your submissions dated July 25 and August 14, 2001.

This supplemental new drug application provides for revised carton and container labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted May 17, 2001, patient package insert submitted May 17, 2001, immediate container and carton labels submitted May 17, 2001). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-005/S-001." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kevin Darryl White, Project Manager, at (301) 827-2020.

Sincerely,

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research